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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/202,104	04/30/1999	LEONARDUS ADRIANUS MARIA VAN LEENGOED	3890US	2481
24247	7590	04/14/2004	EXAMINER	
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			LANDSMAN, ROBERT S	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/202,104	VAN LEENGOED ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,8,9,11,12,15,21,72,74,75 and 78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,4,5,8,9,11,12,15,21,72,74,75,78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Formal Matters

- A. The Amendment dated 1/23/04 has been entered into the record.
- B. Claims 1,4,5,8,9,11,12,15,21,72,74,75 and 78 are pending and are the subject of this Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Specification

- A. The objection to the specification regarding the arrangement of the specification has been withdrawn in view of Applicants' submission of a new specification.
- B. The Brief Description of Fig. 1 should recite "Fig. 1A-1C Amino acid sequence...(respectively)"

3. Claim Objections

- A. All objections to the claims have been withdrawn in view of Applicants' arguments, or amendments to the claims.
- B. The syntax of claim 1 could be improved by (1) removing the parentheses around "SEQ ID NO:1" and removing the phrase "for determining IL-6 antagonistic activity, and said bioassay."

4. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

- A. Claims 1, 4, 5, 8, 9, 11, 12, 15, 21, 72, 74, 75 and 78 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on page 3 of the Office Action dated 10/20/03. Applicants have amended claim 1 to recite "said bioassay comprising contacting IL6-dependent cells with said isolated, recombinant or purified peptide and determining an effect of said isolated, recombinant or purified peptide on IL-6 stimulation of said IL-6-dependent cells."

This argument has been considered, but is not deemed persuasive. The scope of the claims remains excessive with regard to using any and all assays in any and all cells. It appears that the specification is only enabling for determining a **proliferative effect in B9 cells**.

Similarly, **claim 21 is rejected since it is not limited to B9, or mammalian cells**. The claim reads on, for example, E. coli and other cells which are not enabled by the specification.

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B. Claim 74 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of proliferating B9 cells in vitro, does not reasonably provide enablement for a method of exerting any agonist effect on any and all cells which respond to IL-6 in systems other than in vitro, such as in vivo and ex vivo. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims, as written, read on exerting any agonist effect on any cells (e.g. in a patient) for any reason. The breadth of the claims is excessive. Furthermore, the specification does not provide any guidance or working examples of how to practice this method in vivo, or ex vivo, including for what length of time the IL-6 compound will need to be in contact with the cells in order to induce them to proliferate, especially in view of the vast types of cells which are covered by this claim as written, nor does the claim recite what the IL-6 "activity" is which is being elicited. Furthermore, it is not known how to provide the compound at the recited target concentration in the claim since it is not known what organ or tissue this compound is affecting. This treatment is not linked to any disease state. It is also not known how this method could be practiced in vivo to target a specific tissue without causing side-effects in other tissues since IL-6 receptor is abundant in many cell types in the body. Furthermore, it is not clear if the recited IL-6 concentration is the concentration in the syringe, for example, or if this is the concentration that is required to elicit the response in the target tissue (therapeutic dose).

5. Claim Rejections - 35 USC § 112, second paragraph

A. All rejections under 35 USC 112, second paragraph, have been withdrawn in view of Applicants' arguments, or cancellation of the claims. However, new rejections under 35 USC 112, second paragraph, appear below.

B. Claim 12 is confusing since the mixture only comprises one substance. It is not clear how this differs from "composition" as recited in, for example, claims 8, 9 and 11. It is suggested that the claim be amended to recite "a mixture comprising two or more..." or "a mixture comprising at least two..."

C. Claim 15 is confusing since it is not clear how the term "preparation" differs from "composition" as recited in, for example, claims 8, 9 and 11, or "mixture" in claim 12. It is suggested that the claim be amended to recite "a composition comprising..."

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D. Claim 21 is confusing since it recites "a method for culturing cells [by] culturing cells. Furthermore, the claim recites "contacting" whereas the preamble only recites "culturing." It is suggested that the claim be amended as follows:

"A method for culturing mammalian cells comprising incubating said cells in a medium comprising the isolated, recombinant or purified peptide of claim 1."

E. Claim 75 is confusing since, even though the claim has been amended to recite that the peptide composition is associated with an inert carrier, it is still not clear how a "mixture" is different from a "composition" (in this case with an inert carrier).

Advisory information

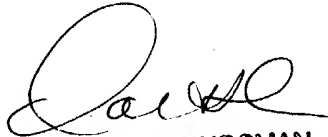
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
April 13, 2004



**ROBERT LANDSMAN
PATENT EXAMINER**